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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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ART UNIT	PAPER NUMBER
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/719,049	REES, JOHN	
	Examiner	Art Unit	
	P. Kathryn Wright	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *75,77,79-90 and 92-102* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *75,77,79-90 and 92-102* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 September 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's Response, filed September 05, 2007, is hereby acknowledged and has been considered. Claims 76, 78, 91 and 103-105 have been cancelled. Claims 75, 77, 79-90, 92-102 are currently pending. Any objection/rejection not repeated herein has been withdrawn by the Examiner.

Drawings

2. The drawings were received on September 05, 2007. These drawings are accepted by the Examiner.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 82 and 84 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 82 and 84 are confusing and indefinite. These claims merely state that the first and second path potentates flow towards the detection zone. It is not clear how this accomplished since no structure is recited in the claims. Clarification is respectfully requested.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 75, 77-90, and 99-102 are again rejected under 35 U.S.C. 102(b) as being anticipated by Bunce et al. (US Patent No. 5,198,193).

Bunce et al., teach an immunoassay analytical test apparatus for screening for the presence of an analyte in a sample of body fluid (i.e., blood; col. 3, line 18; see also, Fig. 5 and Fig. 20 of Bunce et al.) The apparatus of Bunce et al., comprises:

(a) a first flow path 10e including a sample receiving zone for receiving the sample;

(b) a second flow path 20e including non immobilized labeled immunoreactive material that can interact with the analyte;

(c) a mobile phase receiving zone for receiving a mobile phase 61 from a separate container or store 60 (as recited in claims 101, 102). The mobile phase receiving zone being in communication with the first and second flow paths; and

(d) a detection zone 40e including immunoadsorbent 32a for binding the analyte present in the sample.

The detection zone of Bunce et al., is manually moveable (i.e. physically movable) in sequence from a first position in communication with the first flow path through expansible zone 23e to a second position in communication with the second

flow path through expansible zone 24e (as recited in claims 77-78, and 91). Thus, when the detection zone is in its first position there is flow of the sample in the mobile phase from the sample receiving zone to the detection zone, whereby the analyte is allowed to substantially bind with the immunoadsorbent. Furthermore, when the detection zone of Bunce et al., is in its second position there is flow of the labeled immunoreactive material in the mobile phase to the detection zone, whereby the labeled immunoreactive material is allowed to substantially bind to the analyte, so as to provide an indication of the presence of the analyte in the sample (see Bunce et al., beginning at col. 5, lines 24-47.) The various reagents for use with the apparatus are described in Bunce et al., beginning at col. 12, line 32.

With respect to the "Markush-type" claims 79-81, the first flow path includes a material selected from the group consisting of unlabeled immunoreactive material being upstream of the sample receiving zone (see col. 3, lines 20-55).

Regarding claims 82-85, 99-100, the first and second flow paths of Bunce et al., potentiate flow towards the detection zone by capillary action (see col. 1, lines 37-42).

With respect to claims 86-89, written in a Markush format, Bunce et al., teach a material absorbent to the mobile phase as disclosed beginning at col. 1, line 37.

Regarding claim 90, the apparatus of Bunce et al., includes a sink 50 for collection of fluid exiting the detection zone.

7. Claims 75, 77-90, and 99-102 remain rejected under 35 U.S.C. 102(b) as being anticipated by May et al. (US Patent No. 5,275,785).

May et al., teach an immunoassay analytical test apparatus for screening for the presence of an analyte in a sample of body fluid (i.e., blood.) The apparatus of May et al., comprises:

(a) a first flow path 4 including a sample receiving zone for receiving the sample;

(b) a second flow path 3 including non immobilized labeled immunoreactive material that can interact with the analyte (col. 6, lines 55-62);

(c) a mobile phase receiving zone for receiving a mobile phase 61 from a separate container or store 6 (as recited in claims 101, 102.) The mobile phase receiving zone being in communication with the first and second flow paths; and

(d) a detection zone 8 including immunoadsorbent for binding the analyte present in the sample.

The detection zone of May et al., is manually moveable (i.e. physically movable) in sequence from a first position in communication with the first flow path through switch 11 to a second position in communication with the second flow path through expansible switch (as recited in claims 77-78). Thus, when the detection zone is in its first position there is flow of the sample in the mobile phase from the sample receiving zone to the detection zone, whereby the analyte is allowed to substantially bind with the immunoadsorbent. Furthermore, when the detection zone of May et al., is in its second position there is flow of the labeled immunoreactive material in the mobile phase to the detection zone, whereby the labeled immunoreactive material is allowed to substantially

bind to the analyte, so as to provide an indication of the presence of the analyte in the sample.

With respect to the "Markush-type" claims 79-81, the first flow path includes a material selected from the group consisting of unlabeled immunoreactive material being upstream of the sample receiving zone (see col. 6, lines 55-62).

Regarding claims 82-85, 99-100, the first and second flow paths of May et al., potentiate flow towards the detection zone by capillary action (see col. 8, lines 2-4).

With respect to claims 86-89, written in a Markush format, May et al., teach a material absorbent to the mobile phase as disclosed beginning at col. 1, line 37.

Regarding claim 90, the apparatus of May et al., includes a sink 9 for collection of fluid exiting the detection zone.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 92-98 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Bunce et al. (US Patent No. 5,198,193) or May et al. (US Patent No. 5,275,785) in view of Burd et al. (US Patent No. 5,939,331).

The teachings of Bunce et al., and May et al., have been summarized previously, *supra.*

Neither Bunce et al., or May et al., explicitly teach the analyte is allergen specific IgE (claim 92) or the removal of non-IgE components via a matrix or filter located between the sample inlet and the detection zone. However, the use of lateral flow assay for the IgE analyte in whole blood employing a filter is considered conventional in the art, see Burd et al.

Burd et al., teach a lateral flow device for detecting the presence of analytes (including IgE). The flow device includes a filter containing a matrix (i.e., red blood cell binding reagents) located at the sample receiving zone 23 between the sample introduction aperture 35 and the detection zone 29 (see col. 9, line 57- col. 10, line 14 and col. 7, lines 41-51). The filter is designed to remove the red blood cells since whole blood sample may obscure the reading of the test results due to turbidity and color (col. 1, lines 19-20.)

Thus, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to have included in the lateral flow device of Bunce et al., or May et al., the filter containing matrix of Burd et al., in order to remove the red blood cells

since whole blood sample may obscure the reading of the test results due to turbidity and color (col. 1, lines 19-20.)

Response to Arguments

11. Applicant's arguments filed September 05, 2007 have been fully considered but they are not persuasive. Regarding the rejection of claims 82 and 84 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant merely states that these claims "define features provided by the first and second flow paths, respectively, in a clear and concise manner that does not run afoul of 35 USC 112, second paragraph."

The Examiner respectfully disagrees. Claims 82 and 84 are confusing and indefinite since they do not define any features in the first and second path which potentates flow towards the detection zone. Therefore, this rejection is maintained.

With respect to the previous rejection of claims 75-91 and 99-102 under 35 U.S.C. 102(b) as being anticipated by Bunce et al. (US Patent No. 5,198,193) and claims 75-91 and 99-102 under 35 U.S.C. 102(b) as being anticipated by May et al. (US Patent No. 5,275,785), Applicant argues that the hydrated material that is responsible for the movement between flow channels, rather than a "manual movement" as recited in amended claim 75. Furthermore, Applicant alleges that the devices of Bunce et al., are intended to avoid the perceived difficulties associated with the use of devices involving "complex manual procedures". Thus, Applicant concludes that the use of

hydratable expansible materials is intended to render "manual movement" of portions of the device unnecessary.

Specifically, Applicant argues that Bunce et al., and May et al. describe devices that use a "liquid-swellable material" to make or break contact between two liquid-conductive zones. Furthermore, Applicant asserts that "the movement is controlled entirely by hydration and swelling of a material incorporated in the flow path. It is this swelling which causes movement within the device. Were an operator to attempt to manually switch between flow paths before hydration and swelling of the material, this would cause damage of the material, and would prevent function of the flow path as required. Similarly, the operator cannot readily prevent or delay such switching once hydration of the expandable material has occurred."

The Examiner respectfully disagrees with all of Applicant's arguments. First, in response to Applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., an operator which manually switch between flow paths) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Second, the Examiner asserts that the stated purpose of the instant invention is to overcome the problems associated with non-sequential immunometric assays by providing a self diagnosis apparatus which can use a sequential immunoassay method, but which does not require sophisticated laboratory equipment or technical expertise,

see page 4, lines 19-21 of specification as originally filed. This implies the operation of the instant inventive device by an operator is not required.

Lastly, claim 75, as currently amended, recites a detection zone including immunoadsorbent for binding the analyte when the analyte is present in the sample, the detection zone being manually moveable from a first position in communication with said first flow path to a second position in communication with said second flow path. The Examiner asserts the limitation being "manually moveable" does not necessarily mean "movement by an operator". The Examiner looks to the specification for what is meant by the phrase "manually movable". The only support for "manually movable" was found at page 13, lines 19-21, which states that after a specified period of time, typically ten minutes, the second phase of reaction is initiated by the physical movement of the detection zone from the first flow path to the second flow path. This process may be carried out manually or by other means. That is, the phrase "manually movable" is not restricted to movement by an operator. The phrase "manually movable" has been interpreted as "physically movable" by the Examiner. Thus, the devices of Bunce et al. and May et al., do teach a detection zone i.e., liquid-swellable material that is physically movable to make or break contact between two liquid-conductive zones.

Accordingly, for the reasons delineated above, the rejections of claims 75-91, 99-102 under 35 U.S.C. 102(b) is maintained.

Conclusion

12. No claim allowed.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Wright (f.k.a. Bex) whose telephone number is 571-272-2374. The examiner can normally be reached on Monday thru Thursday, 9 AM to 6 PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

pkw

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